



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James Tiedje *et al.*

Serial No.: 10/073,464

Group No.: 1634

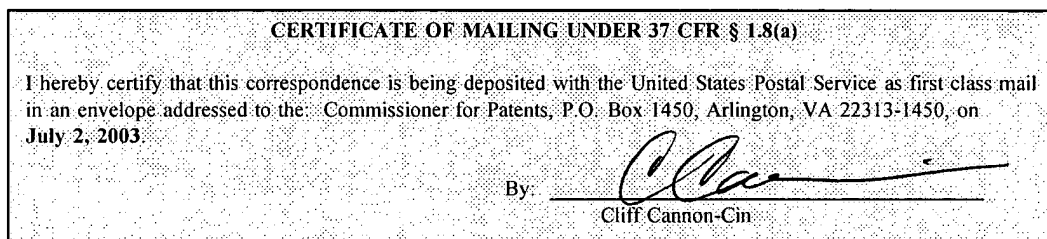
Filed: 02/11/2002

Examiner: Johannsen, D.B.

Entitled: **Microbial Identification Chip Based On DNA-DNA Hybridization**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450



Dear Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 4,683,195 to Mullis *et al.* [1987];
- U.S. Patent No. 4,683,202 to Mullis [1987];
- U.S. Patent No. 4,965,188 to Mullis *et al.* [1990];
- Anderson and Young, "Quantitative Filter Hybridization," in Nucleic Acid Hybridization, Hames and Higgins (eds.) IRL Press Limited, Oxford [1985] title and copyright pages only;
- Chamberlin *et al.*, "New RNA polymerase from *Escherichia coli* infected with bacteriophage T7," *Nature*, 228:227-231 [1970];
- Cho and Tiedje, DNA relatedness of world-wide collection of fluorescent *Pseudomonas* genotypes," Abstracts of the 100th General Meeting of the

American Society for Microbiology, American Society for Microbiology, Washington, DC [2000];

- DeParasis and Roth, "Nucleic acid probes for identification of phytobacteria: Identification of genus-specific 16s rRNA sequences," *Phytopathol.*, 80:618-621 [1990];
- Devereux *et al.*, "Diversity and origin of *Desulfovibrio* species: Phylogenetic definition of a family," *J. Bacteriol.*, 172:3609-3619 [1990];
- Erlich (ed.), PCR Technology, Stockton Press, New York [1989] title and copyright pages only;
- Fox *et al.*, "How close is close: 16S rRNA sequence identity may not be sufficient to guarantee species identity," *Int. J. Syst. Bacteriol.*, 42:166-170 [1992];
- Kacian *et al.*, "A replicating RNA molecule suitable for a detailed analysis of extracellular evolution and replication," *Proc. Natl. Acad. Sci. USA*, 69:3038-3042 [1972];
- Keswani *et al.*, "Phylogeny and taxonomy of mesophilic *Methanococcus* ssp. and comparison of rRNA, DNA hybridization, and phenotypic methods," *Int. J. Syst. Bacteriol.*, 46:727-735 [1996];
- Legendre and Legendre, Numerical Ecology, Elsevier Science, Amsterdam [1998] title and copyright pages only;
- Lessie *et al.*, "Genomic complexity and plasticity of *Burkholderia cepacia*," *FEMS Microbiol. Lett.*, 144:117-128 [1996];
- Martinez-Murcia *et al.*, "Phylogenetic interrelationships of members of the genera *Aeromonas* and *Plesiomonas* as determined by 16S ribosomal DNA sequencing: Lack of congruence with results of DNA-DNA hybridization," *Int. J. Syst. Bacteriol.*, 42:412-421 [1992];
- Misaghi and Grogan, "Nutritional and biochemical comparisons of plant-pathogenic and saprophytic fluorescent pseudomonads," *Phytopathol.*, 59:1436-1450 [1969];
- Moore *et al.*, "The determination and comparison of the 16S rRNA gene sequences of species of the genus *Pseudomonas* (sensu stricto) and estimation

of the natural intrageneric relationships," *Syst. Appl. Microbiol.*, 19:478-492 [1996];

- Palleroni *et al.*, "Deoxyribonucleic acid homologies among some *Pseudomonas* species," *J. Bacteriol.*, 110:1-11 [1972];
- Pecknold and Grogan, "Deoxyribonucleic acid homology groups among phytopathogenic *Pseudomonas* species," *Int. J. Sys. Bacteriol.*, 23:111-121 [1973];
- Pielou, "The measurement of diversity in different types of biological collections," *J. Theor. Biol.*, 13:131-144 [1966];
- Rademaker *et al.*, "Comparison of AFLP and rep-PCR genomic fingerprinting with DNA-DNA homology studies: *Xanthomonas* as a model system," *Int. J. Syst. Evol. Microbiol.*, 50:665-677 [2000];
- Rademaker *et al.*, in Akkermans *et al.*, Molecular Microbial Ecology Manual, Suppl. 3, Kluwer Academic Publishers, Dordrecht, The Netherlands, pp. 1-26 [1998] not provided at this time;
- Sands *et al.*, "Taxonomy of phytopathogenic pseudomonads," *J. Bacteriol.*, 101:9-23 [1970];
- Schena (ed.), Microarray Biochip Technology, Eaton Publishing, Natick, MA [2000] title and copyright pages only;
- Sokal and Sneath, Principles of Numerical Taxonomy, W. H. Freeman & Co., San Francisco [1963] title and copyright pages only;
- Stackebrandt and Goebel, "Taxonomic note: A place for DNA-DNA reassociation and 16S rRNA sequence analysis in the present species definition in bacteriology," *Int. J. Syst. Bacteriol.*, 44:846-849 [1994];
- Stanier *et al.*, "The aerobic pseudomonads: a taxonomic study," *J. Gen. Microbiol.*, 43:159-271 [1966];
- Wayne *et al.*, "Report of the ad hoc committee on reconciliation of approaches to bacterial systematics," *Int. J. Syst. Bacteriol.*, 37:463-464 [1987];
- Weisburg *et al.*, "16S ribosomal DNA amplification for phylogenetic study," *J. Bacteriol.*, 173:697-703 [1991];
- Woese, "Bacterial evolution," *Microbiol. Rev.*, 51:221-271 [1987];

- Wu and Wallace, "The ligation amplification reaction (LAR)-amplification of specific DNA sequences using sequential rounds of template-dependent ligation," *Genomics*, 4:560-569 [1989];
- GenBank Accession No. AE005174 first page of 1209 page document;
- GenBank Accession No. L00026;
- GenBank Accession No. M12239;
- GenBank Accession No. U00096;
- ATCC 9447 *Pseudomonas chlororaphis*;
- ATCC 12633 *Pseudomonas putida*;
- ATCC 13525 *Pseudomonas fluorescens*;
- ATCC 13985 *Pseudomonas aureofaciens*;
- ATCC 15692 *Pseudomonas aeruginosa*;
- ATCC 17397 *Pseudomonas fluorescens*;
- ATCC 17400 *Pseudomonas fluorescens*;
- ATCC 17429 *Pseudomonas aeruginosa*;
- ATCC 17467 *Pseudomonas fluorescens*;
- ATCC 17811 *Pseudomonas chlororaphis*;
- ATCC 33512 *Pseudomonas fluorescens*; and
- LMG 5039 *Pseudomonas marginalis*.

In addition, Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent Nos. 5,800,992 to Fodor *et al.* [1998], 5,871,928 to Fodor *et al.* [1999], and 5,925,525 to Fodor *et al.* [1999] disclose methods and apparatus for sequencing, fingerprinting and mapping biological macromolecules. In particular, Fodor and colleagues disclose the use of specific recognition reagents (*e.g.*, oligonucleotide probes or sequence fragments) synthesized or attached at known locations to a single substrate (*e.g.*, solid support) and capable of hybridizing to specific targets (*e.g.*, DNA), which may be labeled in order to positionally define the interactions between the target and the recognition reagents. However, arrayed elements comprising amplified

genomic sequences from a plurality of bacterial species are not taught in enabling examples;

- U.S. Patent 6,001,564 to Bergeron *et al.* [1999] disclose methods and DNA sequences for identification of common bacterial pathogens. In particular, Bergeron *et al.* disclose species-specific and universal (*e.g.*, 16S or 23S rRNA genes) bacterial sequences for use as probes and amplification primers to detect target bacterial DNAs in solution or attached to a solid support. However, arrayed elements comprising amplified genomic sequences are not taught in enabling examples;
- U.S. Patent 6,004,755 to Wang [1999] discloses methods and kits for quantitative gene expression analysis with microarrays. In particular, Wang discloses hybridizing target and standard cDNAs to an array of probes (*e.g.*, 10 to 1000 nucleotides in length) which may comprise PCR amplified fragments from cDNA templates attached to a solid support. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- PCT Application WO 97/29212 to Gingeras *et al.* [1997] disclose methods, arrays and computer programs for genotyping an organism. In particular, Gingeras *et al.* teach hybridizing a target nucleic acid sequence (*e.g.*, fragmented RNA amplicons) from a first organism to an array of oligonucleotides probes (*e.g.*, 5 to 25 nucleotides in length) corresponding to sequences (*e.g.*, rRNA and/or antibiotic resistance sequences) of a second organism (*e.g.*, *Mycobacterium tuberculosis*) positioned at known locations on a substrate. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- PCT Application WO 00/52203 of French *et al.* [2000], and Anthony *et al.*, "Rapid diagnosis of bacteremia by universal amplification of 23S ribosomal DNA followed by hybridization to an oligonucleotide array," *J. Clin. Microbiol.*, 38: 781-788 [2000] disclose methods, oligonucleotides, solid supports and diagnostic kits for identifying bacteria, comprising primers for amplifying a bacterial target sequence (*e.g.*, 23S rRNA gene). In particular,

these investigators teach hybridization of the amplified target DNA sequence to an array of oligonucleotide probes (*e.g.*, 21-30 nucleotides in length) which may be immobilized on a solid carrier. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;

- Affymetrix GeneChip® *E. coli* Genome Array Product Information (http://www.affymetrix.com/products/gc_ecoli_content.html) discloses bacterial microarrays for expression analysis. In particular, enriched prokaryotic mRNA is hybridized to a GeneChip array comprising 25 mer oligo probes corresponding to various *E. coli* open reading frames and intergenic regions. However, methods and kits for bacterial identification comprising as arrayed elements, amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Behr *et al.*, "Comparative genomics of BCG vaccines by whole-genome DNA microarray," *Science* 284: 1520-1523 [1999] disclose the use of a *Mycobacterial tuberculosis* H37Rv microarray composed of amplified sequences from predicted ORFs to examine *Mycobacterial bovis* sequence divergence. In particular, labeled genomic DNA of a first bacterial species (*M. tuberculosis*) and of a second bacterial species (*M. bovis*) were simultaneously hybridized to a microarray of sequences from the first bacterial species. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Cummings and Relman, "Using DNA microarrays to study host-microbe interactions," *Emerg. Infect. Dis.*, 6: 513-525 [2000] review the utility of DNA microarrays constructed by physically attaching DNA fragments (*e.g.*, library clones or PCR products) to a solid substrate and to DNA microarrays constructed by synthesizing single-stranded oligonucleotides *in situ*. Bacterial microarrays were discussed in the context of RNA expression profiling and to a limited extent in DNA genotyping. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;

- Fawcett *et al.*, "The transcriptional profile of early to middle sporulation in *Bacillus subtilis*," *Proc. Natl. Acad. Sci. USA*, 97: 8063-8068 [2000] disclose the use of arrays composed of amplified ORF sequences from *B. subtilis* to examine gene expression during sporulation in wild type and mutant *B. subtilis* cells. However, methods and kits for bacterial identification comprising as arrayed elements, amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Gingeras *et al.*, "Simultaneous genotyping and species identification using hybridization pattern recognition analysis of generic *Mycobacterium* DNA arrays," *Genome Research*, 8:435-448 [1998] disclose the use of arrays comprising oligonucleotides corresponding to the sequence of the *Mycobacterium tuberculosis rpoB* gene to examine sequence diversity at this locus in 10 mycobacterial species. In particular, Gingeras *et al.* teach hybridizing a target nucleic acid sequence (*e.g.*, fragmented RNA amplicons) from a first mycobacterial species to an array of oligonucleotides probes (*e.g.*, 5 to 25 nucleotides in length) corresponding to sequences of a second mycobacterial species. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Gordon *et al.*, "Identification of variable regions in the genomes of tubercle bacilli using bacterial artificial chromosome arrays," *Mol. Microbiol.*, 32: 643-655 [1999] disclose the construction of a *Mycobacterial tuberculosis* H37Rv array composed of restriction digested BACs, immobilized to a nitrocellulose membrane after electrophoresis through an agarose gel. In particular, the array was repeatedly used to examine the hybridization profile of labeled genomic DNA from several mycobacterial species (*e.g.*, Southern blot method). However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Hayward *et al.*, "Shotgun DNA microarrays and stage-specific gene expression in *Plasmodium falciparum* malaria," *Mol. Microbiol.*, 35: 6-14 [2000] disclose the construction of microarrays comprising PCR-amplified fragments of

genomic DNA from *P. falciparum* to analyze gene expression by hybridization of labeled target cDNA from trophozoites and gametocytes. However, methods and kits for bacterial identification comprising as arrayed elements, amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;

- Khodursky *et al.*, "Analysis of topoisomerase function in bacterial replication fork movement: Use of DNA microarrays," *Proc. Natl. Acad. Sci. USA*, 97: 9419-9424 [2000] disclose the use of microarrays comprising PCR-amplified *E. coli* ORF probes to analyze DNA replication by hybridization of labeled target DNA from replicating bacteria and labeled reference DNA from nonreplicating bacteria. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Kuipers, "Genomics for food biotechnology: prospects of the use of high-throughput technologies for the improvement of food microorganisms," *Curr. Opinion Biotechnology*, 10: 511-516 [1999] briefly reviews the use of various functional genomics technologies in food microbiology applications. In particular, Kuipers describes the use of DNA microarrays containing oligonucleotides or ORF amplicons as probes to analyze bacterial transcriptomes (*e.g.*, differential gene expression and global gene regulation). In addition, Kuipers contemplates the production of DNA microarrays for genotyping food pathogens. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not disclosed, and no working examples are provided;
- Kuipers *et al.*, "DNA-microarrays and food-biotechnology," *Antonie van Leeuwenhoek* 76: 353-355 [1999] briefly describe DNA microarrays comprising amplicons of bacterial ORFs or synthetic oligonucleotides for analyzing transcription profiles of wild type and mutant *Bacillus subtilis* (*e.g.*, labeled cDNA as a target). In addition, the development of DNA arrays for identification of spoilage bacteria is contemplated. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not disclosed, and no working examples are provided;

- Socransky *et al.*, "'Checkerboard' DNA-DNA hybridization," *BioTechniques* 17: 788-792 [1994] disclose the identification of bacteria by using "Minislot" and "Miniblotter" devices. In particular, Socransky *et al.* immobilize as a target, whole DNA from a plurality of bacterial species via a "Minislot" device, followed by hybridization to digoxigenin-labeled whole genomic DNA probes and/or to alkaline phosphatase 16S rRNA oligonucleotide probes with a "Miniblotter" device. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples; and
- Troesch *et al.*, "*Mycobacterium* species identification and rifampin resistance testing with high-density DNA probe arrays," *J. Clin. Microbiol.*, 37: 49-55 [1999] disclose the identification of bacteria by using as a target, fragmented RNA transcribed *in vitro* from PCR-amplified bacterial nucleic acid, for hybridization to an Affymetrix GeneChip microarray comprising a multitude of synthetic oligonucleotide probes corresponding to 16S rRNA, *rpoB*, and *katG* mycobacterial sequences. However, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples.

The following documents were cited in the International Search Report in a related Application WO 02/101094 A1:


- U.S. Patent No. 6,228,575 to Gingeras *et al.* [2001] disclose methods, arrays and computer programs for genotyping an organism. In particular, this patent is related to PCT Application WO 97/29212 to Gingeras *et al.* [1997] and is relevant for the reasons discussed above. Likewise, arrayed elements comprising amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;
- Ahern, "Biochemical reagent kits offer scientists good return on investment," *The Scientist*, 9:20 [1995] discloses that pre-made biochemical and molecular biology reagents (restriction enzymes) and kits are found to be both time and cost effective by many investigators. However, methods and kits for bacterial

identification comprising as arrayed elements, amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples;

- Cho and Tiedje, "Bacterial species determination from DNA-DNA hybridization by using genome fingerprints and DNA microarrays," *Appl. Env. Microbiol.*, 67:3677-3682 [2001] disclose methods for the identification of bacteria using labeled genomic and reference DNA which are hybridized to arrays of amplified genomic sequence from multiple *Pseudomonas* species. However, this reference by the Applicants is not prior art as it was published after the priority date of the present application; and
- Hoffner, "Pulmonary infections caused by less frequently encountered slow-growing environmental mycobacteria," *European Journal of Clinical Microbiology and Infectious Diseases*, 13:937-941 [1994] provides a general review of human pulmonary infections by mycobacterial species present in the environment. Hoffner indicates that mycobacteria can be identified by standard morphological and biochemical techniques and by genotyping. However, methods and kits for bacterial identification comprising as arrayed elements, amplified genomic sequences from a plurality of bacterial species are not taught in enabling examples.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: July 2, 2003



Christine A. Lekutis
Registration No. 51,934

PATENT

Attorney Docket No. **MSU-06787**

Please direct future inquiries to:

Peter G. Carroll
Registration No. 32,837

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415/904-6500

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: MSU-06787	Serial No.: 10/073,464			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)				Applicant: James Tiedje <i>et al.</i>				
(37 CFR § 1.98(b))				Filing Date: 02/11/2002	Group Art Unit: 1634			
U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date	
	1	4,683,195	07/28/87	Mullis <i>et al.</i>	435	6	02/07/86	
	2	4,683,202	07/28/87	Mullis	435	91	10/25/85	
	3	4,965,188	10/23/90	Mullis <i>et al.</i>	435	6	06/17/87	
	4	5,800,992	09/01/98	Fodor <i>et al.</i>	435	6	06/25/96	
	5	5,871,928	02/16/99	Fodor <i>et al.</i>	435	6	06/11/97	
	6	5,925,525	07/20/99	Fodor <i>et al.</i>	435	6	04/03/98	
	7	6,001,564	12/14/99	Bergeron <i>et al.</i>	435	6	09/11/95	
	8	6,004,755	12/21/99	Wang	435	6	04/07/98	
	9	6,228,575	05/08/01	Gingeras <i>et al.</i>	435	5	02/07/97	
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	10	WO 97/29212	08/14/97	Gingeras <i>et al.</i>	C12Q	1/68		
	11	WO 00/52203	09/08/00	French <i>et al.</i>	C12Q	1/68		
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	12	Anderson and Young, "Quantitative Filter Hybridization," in <u>Nucleic Acid Hybridization</u> , Hames and Higgins (eds.) IRL Press Limited, Oxford [1985] title and copyright pages only						
	13	Chamberlin <i>et al.</i> , "New RNA polymerase from <i>Escherichia coli</i> infected with bacteriophage T7," <i>Nature</i> , 228:227-231 [1970]						
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Examiner:				Date Considered:				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)					
	25	Moore <i>et al.</i> , "The determination and comparison of the 16S rRNA gene sequences of species of the genus <i>Pseudomonas</i> (sensu stricto) and estimation of the natural intragenetic relationships," <i>Syst. Appl. Microbiol.</i> , 19:478-492 [1996]			
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	55	LMG 5039 <i>Pseudomonas marginalis</i>			
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